



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,267	10/31/2001	Lakshmi Rambhatla	093/004P	1874

22869 7590 06/06/2005

GERON CORPORATION
230 CONSTITUTION DRIVE
MENLO PARK, CA 94025

EXAMINER

TON, THAIAN N

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/001,267

Applicant(s)

RAMBHATLA ET AL.

Examiner

Thaian N. Ton

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 May 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 13-40.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.

Joe Waites
AU 1632

Continuation of 3. NOTE: The amendments to the claims raise new issues of search and/or consideration because the recitation of "an effective concentration" of a histone deacetylase inhibitor, and the production of at least about 40% of specific differentiated cells would require new considerations under 112, 1st and 102/103.

With regard to the obviousness type double patenting rejection, Applicants argue that with regard to copending application, 10/087,142 the prosecution of the present application is far more advanced, and no T/D is required. Applicants argue that with regard to the requirement for terminal disclaimer over the '589 patent, Applicants argue that the Office has applied the one-way test backwards, because the question is not whether the claims in the issued patent are obvious with respect to the claims here, but whether, the method claimed is obvious with respect to the product claimed in the issued patent. Thus, Applicants argue that the methods instantly claimed require the use of a histone deacetylase inhibitor as an ingredient in the method, whereas there is no recitation of this ingredient in the allowed claims. This is not found to be persuasive. The '589 claims are directed to products, which do not exclude anything else, therefore anything at all could be there. It is appropriate to consult the disclosure to determine what else is there. Based upon the instant specification, sodium butyrate is inherently in the mixture.

Applicants argue that the claims are enabled because the specification exemplifies concentrations of butyrate that are effective, and should the reader deviate from these concentrations, this can be done without undue experimentation. Furthermore, Applicants argue that one of skill can determine, as a matter of routine experimentation, what other histone deacetylase inhibitors are effective in making hepatocyte lineage cells from pPS cells, and point to Table 7 and 8. Particularly, that Trichostatin A induces the hepatocyte phenotypes to various levels of expression of particular markers, and that various other histone deacetylase inhibitors are capable of producing the hepatocyte phenotype. This is not persuasive. Table 7 merely shows tested histone deacetylase inhibitors can cause hepatocyte differentiation, but the breadth of "histone deacetylase inhibitor" is not enabled because there is no indication as to what percentage of cells are differentiated into hepatocytes. With regard to Table 8, the specification teaches that trichostatin A produces cells that express 41% albumin, 81% alpha1-antitrypsin, >70% CK18 and >90% CK19 expression. This is not found to be enabling because the claims require that the cells have at least three of the characteristics listed in independent claim 13. It is unclear from the results presented in Table 8 that the 41% of cells that express albumin also express the other markers. The specification's working examples, with regard to butyrate, and in particular, 5 mM, is found to be enabling in view of the working examples, guidance provided in the specification, and the teachings in the art. Specific embodiments further limit the claims (such as claims 14-15) to recite that 60% of the cells have "at least 5 of the characteristics" and at least 80% of the cells have "at least 7 of the characteristics". These are not found to be enabling for the breadth of utilizing any particular histone deacetylase inhibitor, in any concentration. Table 8 fails to provide any guidance for these limitations, with regard to Trichostatin A. Thus the prior rejection of record is maintained.